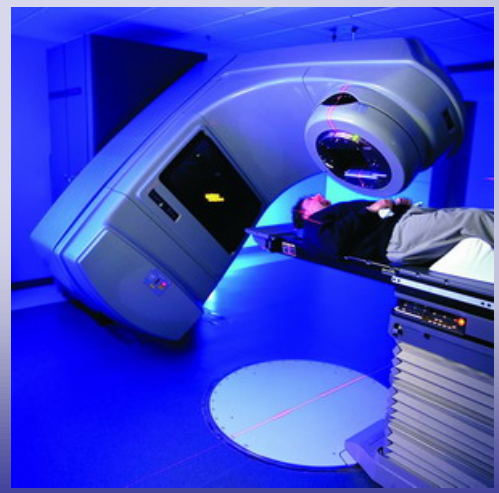
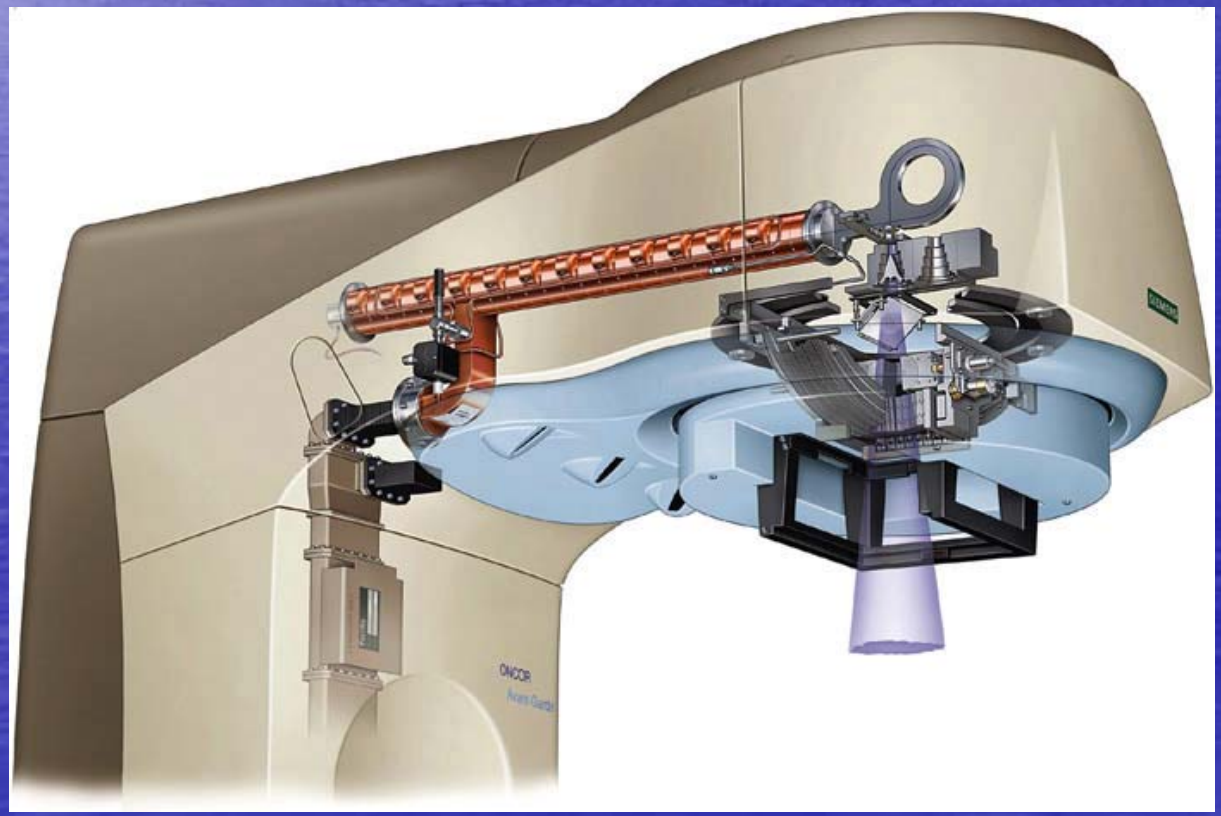

CAUTION
THIS SIGN HAS
SHARP EDGES
DO NOT TOUCH THE EDGES OF THIS SIGN
ALSO, THE BRIDGE IS OUT AHEAD

Brent Gordy, KDHE
Overview of Part 14 of the Kansas Radiation Protection Regulations (KRPR)

Therapeutic Radiation Machines



Why Radiation Therapy “Machine”? (KRPR separates machine produced x-rays from radioactive material produced gamma rays)



- Some Definitions:
- “Registrable Item”: any radiation machine, i.e, x-ray including linear accelerators.
- “Licensed material”: radioactive material
- A facility may be a registrant, a licensee or both.
- Part 14 is applicable to machine produced radiation, thus the regulations refer to “registrants”.
- Registrant can be a hospital, clinic, private office

Part 14
28-35-450
Therapeutic Radiation Machines
"General Requirements"

The KRPR have adopted the provisions of Part X of "The Suggested State Regulations for Control of Radiation"

Where Do You Find Part 14?

- Go to http://www.kdheks.gov/radiation

The Kansas Department of Health and Environment

Kathleen Sebelius, Governor - Roderick L. Bremby, Secretary
Curtis State Office Building 1000 SW Jackson Topeka, KS. 66612
(785) 296-1500 FAX:(785)368-6368 Email:info@kdhe.state.ks.us

KDHE Search:

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Links

Radiation Home

Program Contacts

Asbestos and X-ray Compliance

Environmental Radiation, Emergency Preparedness, and Right-to-Know

Kansas Radon Program

Radioactive Material and Licensing

Program Regulations

Program Resources

Radiation

Mission: *Our mission is to protect the well being of Kansans and the environment from the harmful effects of man made and natural radiation. Through competent and efficient utilization of our services and enforcement, we strive to minimize unnecessary radiation exposure. We advance our mission by dedicating these efforts to our valued and respected Kansans.*

Register Now!

Radiation Control Program 2006 Workshop

December 6-7, 2006, Wednesday and Thursday

Ramada Hotel Topeka, Kansas

Kansas Department of Health and Environment, Bureau of Air and Radiation will be holding the Radiation Control Program 2006 Workshop this December. Members of the regulated community will find this an excellent resource for learning about recent changes in the Radiation Protection Regulations and topical presentations from the Medical and Industrial sectors. ASRT continuing education credit will be requested by KDHE. The registration fee of $85 will cover both days and include lunch, snacks, and an evening social on Wednesday night. Late registration fee is $100 after November 22, 2006.

Links

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Helpful Links

Department of Health and Environment and published by the Kansas Secretary of State. These rules are taken from electronic copies of the printed state regulations which serve as the agency's official rules and regulations. The printed regulations represent the final word in matters of interpretation.

Click on the following link to the electronic facsimile of the Kansas Administrative Regulations:

Kansas Department of Health and Environment, Standards for Protection Against Radiation

- Part 1. General.
- Part 2. Registration of Radiation Producing Devices.
- Part 3. Licensing of Sources of Radiation.
- Part 4. Standards for Protection Against Radiation.
- Part 5. Use of X-rays in the Healing Arts.
- Part 6. Use of Radioactive Materials in the Healing Arts.
- Part 7. Special Requirements for Industrial Radiographic Operations.
- Part 8. Radiation Safety Requirements for Analytical X-ray Equipment.
- Part 9. Radiation Safety Requirements for Particle Accelerators.
- Part 10. Notices, Instructions and Reports to Worker: Inspections.
- Part 11. Wireline and Subsurface Tracer Studies
- Part 12. Licensing and Radiation Safety Requirements for Irradiators
- Part 13. Contingency Planning for Response to Radioactive Material Emergencies
- Part 14. Therapeutic Radiation Machines
- Part 15. Packaging and Transportation of Radioactive Material

The Kansas Department of Health and Environment, Standards for Protection Against Radiation include adoption by reference of certain of the Parts. The documents that were adopted by reference can be accessed by clicking on the appropriate link.

KDHE Part	Adoption by Reference resource
Part 6	10 CFR Part 35
Part 12	10 CFR Part 36
Part 14	Suggested State Regulations for Control of Radiation Part X

Click on the following links to go to the electronic facsimile of the appendices:

SUGGESTED STATE REGULATIONS PART X (This is a PDF document so you must scroll down to Part X)

PART X - THERAPEUTIC RADIATION MACHINES

Section X.2 “Definitions” do not apply as our definitions in Part 1 of the KRPR are applicable.

The real “substance of the regs” starts on page X6.

- I. Administrative
- II. Technical/Operating Procedures
- III. Shielding/Plan Reviews
- IV. Quality Management

I. Administrative Controls

- Registrant is responsible for directing the operation of the machines and ensuring that the requirements of Part X are met.

- The registrant designates who will be the "authorized user" of the machines.

AUTHORIZED USER (AU)

- “A practitioner of the healing arts who is designated by the registrant as a user of the x-ray machine or accelerator”

EXTERNAL BEAM TRAINING REQUIREMENTS FOR THE AU

- Certified in:
  - Radiology or therapeutic radiology by the American Board of Radiology or
  - Radiation oncology by the American Osteopathic Board of Radiology or
  - Radiology with specialization in radiotherapy as a British "Fellow of the Faculty of Radiology" or "Fellow of the Royal College of Radiology" or
  - Therapeutic radiology by the Canadian Royal College of Physicians and Surgeons

OR

- IS IN THE ACTIVE PRACTICE OF THERAPEUTIC RADIOLOGY AND HAS:

  - Completed 200 hours of instruction in basic radiation techniques applicable to external beam radiation therapy
  - Completed 500 hours of supervised work experience
  - A minimum of 3 years of supervised clinical experience

Pages X7-X8 further elaborate the specific requirements of the above.

- *A physician shall not act as an AU for any therapeutic radiation machine until such time as his/her training has been reviewed and approved by the department (KDHE)*

VISITING AUTHORIZED USER

- Registrant may permit any physician to act as a visiting AU for up to 60 days in any calendar year if:
  - The visiting AU has written permission of the registrant
  - The visiting AU meets the training requirements of the AU
  - The registrant keeps copies of all records regarding the visiting AU for 5 years from the date of his/her last visit

RADIATION THERAPY PHYSICIST (TP)

- May or may not report to the AU depending on the reporting structure of the registrant.

- *Must be registered with the department (KDHE) as a provider of services for external beam radiation therapy units.*

TRAINING FOR THE TP

- Must be certified by the American Board of Radiology in:
  - Therapeutic radiological physics or
  - Roentgen-ray and gamma-ray physics or
  - X-ray and radium physics or
  - Radiological physics

OR

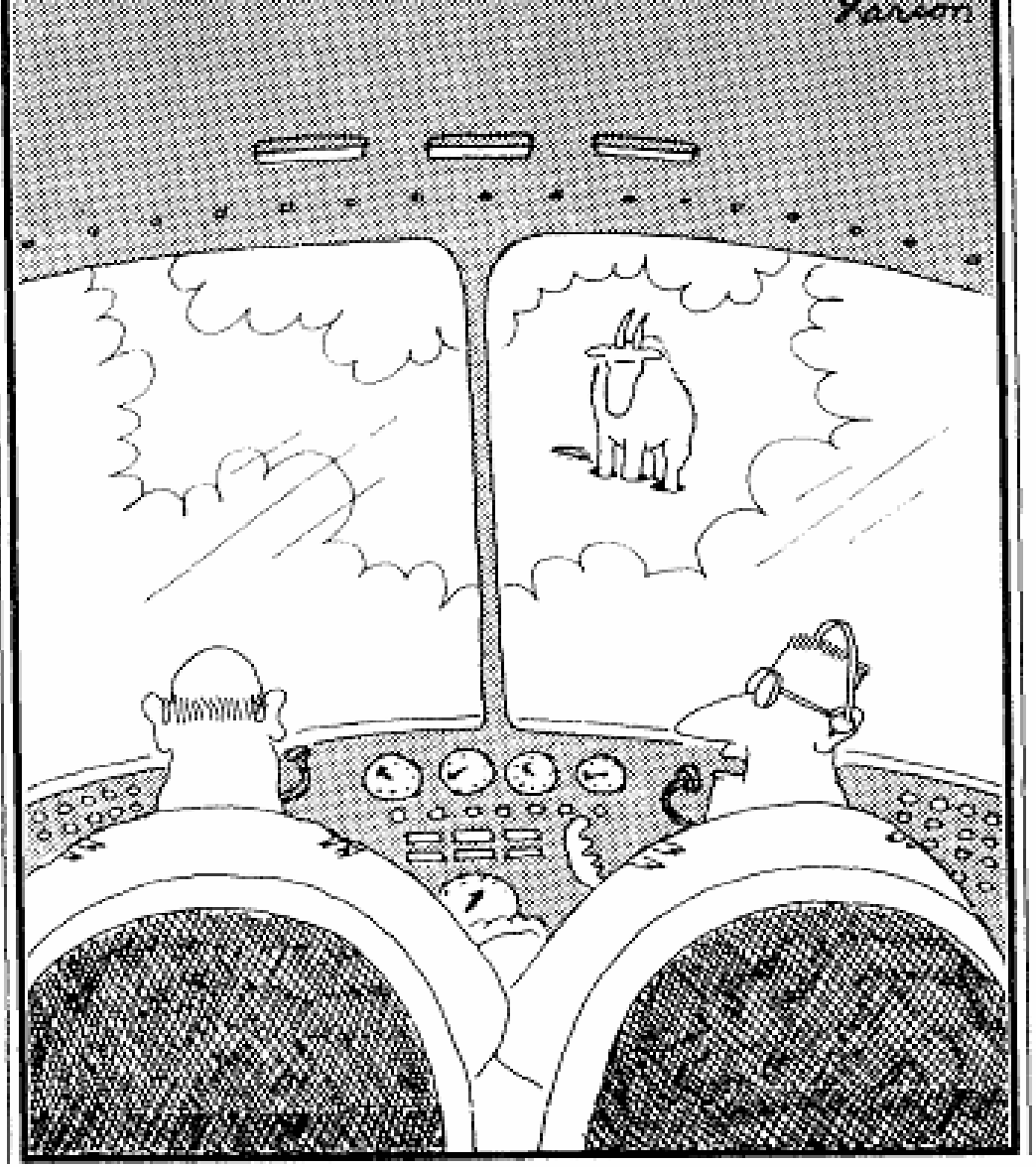
- Be certified by the American Board of Medical Physics in Radiation Oncology Physics or
- Be certified by the Canadian College of Medical Physics or
- Have a master's or doctor's degree in physics, biophysics, radiological physics, or health physics and have completed:
  - 1 year of full time training in therapeutic radiological physics and also 1 year of full time work experience under the supervision of a radiation therapy physicist at a medical institution

OPERATOR QUALIFICATIONS RTT

- Individuals operating a therapeutic machine for healing arts purposes shall meet the requirements specified in the radiologic technologists practice act. Effective 10/1/05
- Must be able to demonstrate familiarity with written safety rules as developed by the TP

MAINTENANCE RECORD AND INFORMATION FOR EACH MACHINE

- Registrant must have available for inspection by KDHE:
  - Acceptance testing records
  - Records of all surveys, calibrations, and quality assurance checks with name of person who performed
  - Signature of person authorizing return of machine to clinical use after service, repair, or upgrade.
  - Records must be retained until disposal is authorized by KDHE



"Say . . . What's a mountain goat doing way up here in a cloud bank?"

II. Technical Requirements

- Protection Surveys
  - New/modified facilities and/or machines must be surveyed by physicist with a calibrated survey instrument. Machine must be set to the largest treatment field and scattering phantom utilized to assure:
  - Radiation levels in restricted and unrestricted areas do not exceed levels as specified in Part 4 of the KRPR.
  - If levels per Part 4 are likely to be exceeded the machine may not be used until additional shielding or interlocks are provided.

PART 4 BASIC REVIEW

- ALARA (As Low As Reasonably Achievable) principle must be followed

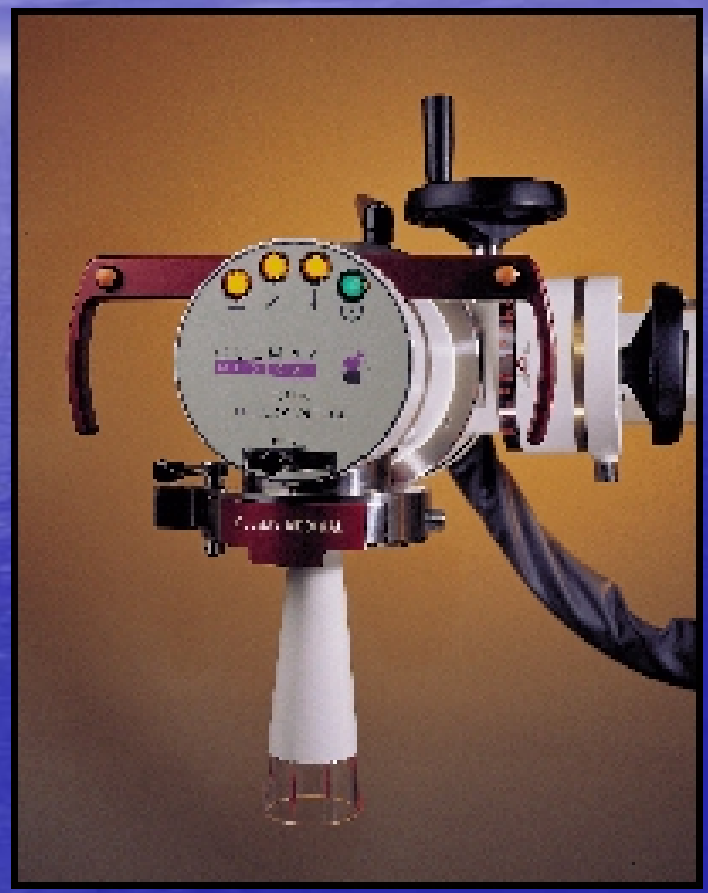
- Occupational dose limits:
  - 5 Rem/yr. (0.05Sv/yr.) total effective
  - 0.5 Rem/yr. (5 mSv/yr.) to embryo/fetus

- General public dose limits
  - 0.1 Rem/yr (1mSv/yr.)

DOSIMETRY EQUIPMENT

- Equipment shall have been calibrated within the last 24 months and after servicing
  - For beam energies >1MV the equipment shall be calibrated to Cobalt-60
  - For <1MV calibrate to the energy being measured
- Shall have a dosimetry system for QA checks.
  - QA equipment must have been calibrated within the previous 12 months and after servicing

MACHINES LESS THAN 500 KV



<500KV SUMMARY

- Leakage Radiation
- Permanent Beam Limiting Devices
- Adjustable or removable beam limiting devices
- Filters
- Tube immobilization
- Source (focal spot) marking
- Beam block
- Timer
- Target-to-skin-distance (TSD)
- Shutters

- Low filtration indicator
- Control panel
  - Power on
  - X-ray production indicator
  - Tube current/voltage indicator
  - Timer
  - Locking device
- Verbal/visual communications
- Control location
- Door interlocks
- Calibrations (every 12 months), after repair or when QA check shows>5% difference
- QA Checks required monthly

- Machine to be “secured” if left unattended
- >150KV then no one other than patient allowed in room
- <150KV then personnel can be in room but must be behind adequate barriers (Part 4 limits)
- <50KV tube housing can be handheld if lead gloves/apron worn (>0.5mm lead equivalent)

- Calibrated portable survey instrument required (1mR/hr.-1000mR/hr. minimum range)


What we say to dogs
Okay, Ginger! I've had it! You stay out of the garbage! Understand, Ginger? Stay out of the garbage, or else!
What they hear
blah blah GINGER blah blah blah blah blah blah GINGER blah blah blah blah blah...

PHOTON/ELECTRON MACHINES >500KV REQUIREMENTS

- Leakage radiation
  - Outside the useful beam
  - Through beam limiting devices
  - How measured

- Filters/Wedges: operational/ID requirements
- Stray radiation from electron beam striking surfaces
- Beam monitors required
  - Redundant/independently powered

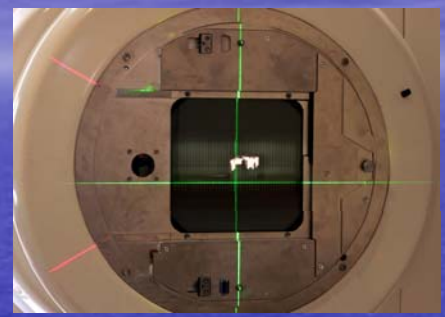
- Beam symmetry (defined specifications)
- Display of monitor units selected
- Absorbed dose rate termination capability (prescribed or exceeding prescribed dose)
- Termination of irradiation at any time
- Interruption of irradiation and restart
- Timer
- Selection of radiation type and applicable interlocks
- Energy selection capability
- Selection of stationary or moving beam with related interlocks

FACILITY DESIGN REQUIREMENTS >500KV

- Protective barriers
- Control panel
- Viewing systems
- Audio/oral communication systems
- Room entrances/interlocks
- Beam interceptor interlocks
- Emergency cutoff switches
- Safety interlocks
- Surveys for residual radiation from photon-neutron production

PHYSICIST SUPPORT

(Services of a physicist required in facilities having machines >500KV)



- Responsible for:
  - Calibrations and protection surveys
  - Supervision of dosimetry
  - Beam data acquisition and transfer to dosimetry
  - Quality assurance
  - Consults with AU in treatment planning as needed
  - Performs calculations/assessments involving misadministrations

ACCEPTANCE TESTING

- Performed by physicist
- In accordance with AAPM Code of Practice
- Done before first use or after reinstallation or

  1-whenever QA checks indicate output difference from calibration is >5%

  2-whenever any component replacement, repair, or modification occurs which could affect the beam characteristics

PERIODIC QUALITY ASSURANCE CHECKS

- Must include:
  - Central axis radiation output
  - Room entrance interlocks
  - Beam on interruption/termination
  - Beam on indicator lights
  - Viewing systems
  - Electrically operated treatment room doors
  - Emergency power cutoff switches
- Perform weekly or more often
- Physicist must stop machine operation if any parameter is out of tolerance

III. RADIATION SHIELDING AND SHIELDING PLAN REVIEWS

- Plans must be submitted to KDHE before install or when installing a machine of higher energy than previously installed
- Plan must include:
  - Facility name, address, phone number, new or modified facility, name of person doing plan
  - Drawing showing primary/secondary barriers and structural composition
  - Machine parameters, weekly radiation output in rads at 1 meter, total beam ontime/week
  - Type of occupancy of all adjacent areas
  - Description of any assumptions made
  - Sample calculation of methodology used to determine amount of shielding required

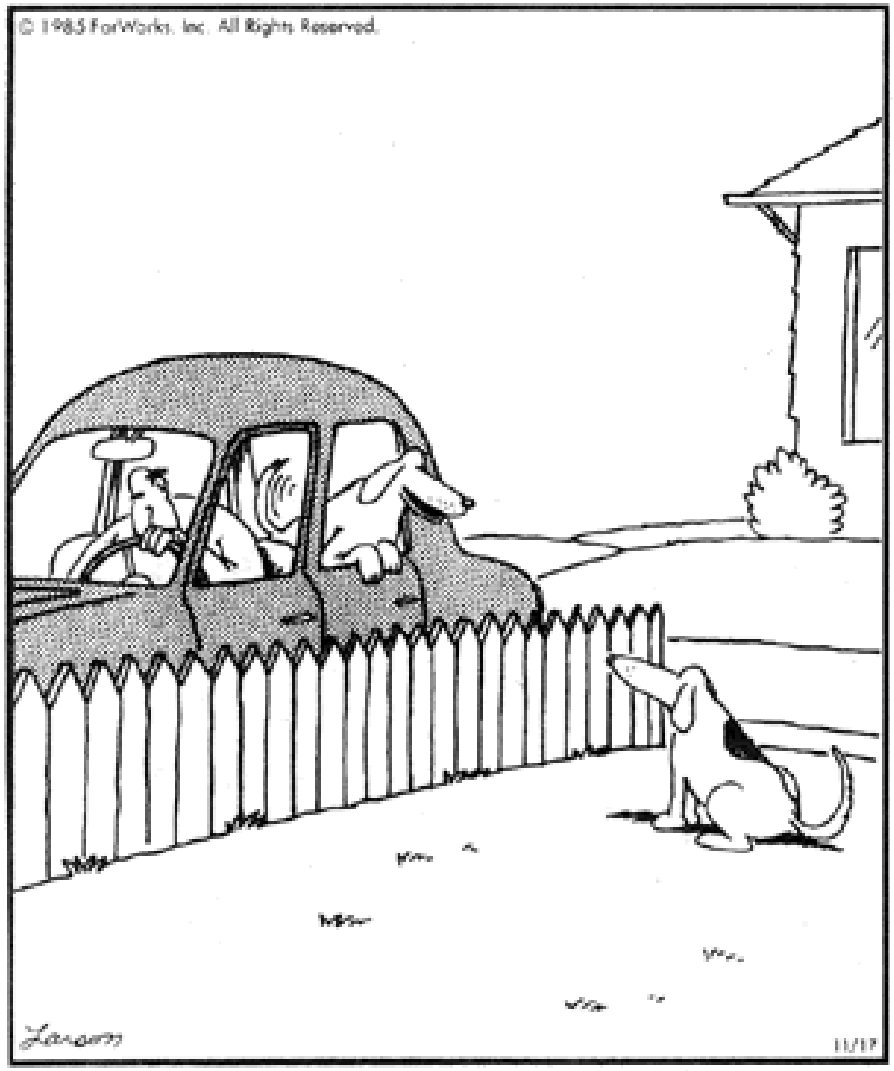
NEUTRON SHIELDING PLANS

- Required for >10MV photon machines
- Info required:
  - Structural composition, thickness, density, and location of all neutron shielding material
  - Description of all assumptions used in neutron shielding calculations
  - Sample calculation showing the methodology used to determine the amount of neutron shielding required
  - Method and instrumentation that will be used to verify the shielding adequacy

THE FAR SIDE® by GARY LARSON

From ***The Complete Far Side***, available in bookstores

Original release date: 5/25/85



"Ha ha ha, Biff. Guess what? After we go to the drugstore and the post office, I'm going to the vet's to get tutored."

IV. WRITTEN QUALITY MANAGEMENT PROGRAM (QMP)

- Required of registrant
- May use one like that shown in Appendix B or C
- Must submit to KDHE a certification that a QMP exists
- Specifies staff, duties, responsibilities, and procedures

GENERAL WRITTEN REQUIREMENTS OF THE QMP:

- Written, dated, signed, directive by the AU of the prescribed dose prior to administration
- Or of changes to the prescribed dose
- Patient's ID is verified by more than one method
- Any unintended deviation from the prescribed dose is identified, evaluated, and steps to prevent recurrence are established

QMP DEFINITIONS

- "Misadministration" means the administration of an external beam radiation therapy dose
  - 1-involving the wrong patient
  - 2-when the treatment is = or < 3 fractions and the administered total dose differs from the prescribed dose by >10%
  - 3-when the weekly administered dose differs from the weekly prescribed dose by >30% of the prescribed dose
  - 4-when the total dose administered differs from the total prescribed dose by >20% of the prescribed dose

- "Recordable event" means the administration of an external beam radiation therapy dose
  - When the weekly administered dose differs by >15% of the weekly prescribed dose

SPECIFIC REQUIREMENTS OF THE QMP

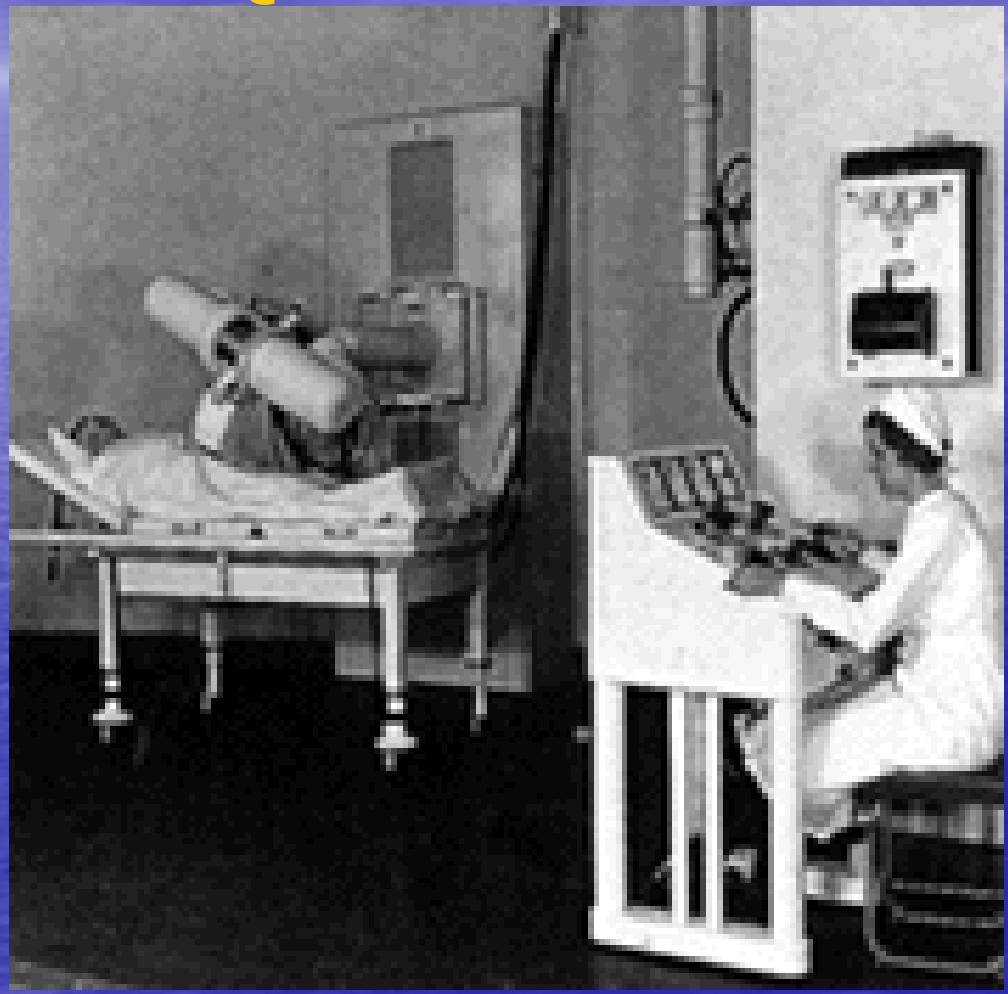
- Review of QMP every 12 months. Include a representative sample of patients treated and all recordable events and misadministrations.
- Keep records of the review for 3 years
- Evaluate and respond to recordable events. Identify why the event occurred and what action is needed to prevent recurrence.
- Keep written directives and records of delivered doses for 3 years.

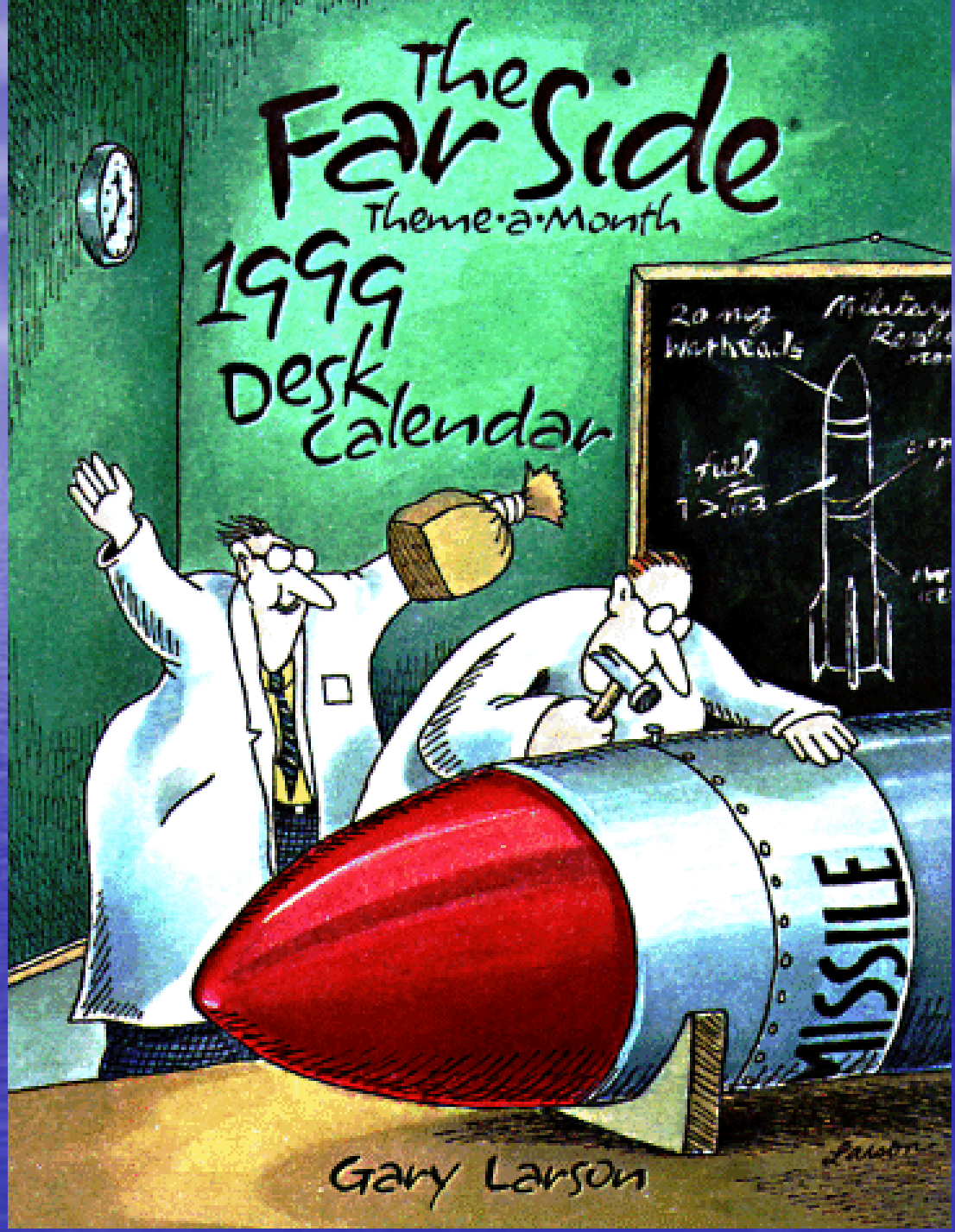
- Evaluate each misadministration and
  - Notify KDHE by phone no later than the next day after its discovery
  - Submit a written report to KDHE with 15 days of the discovery with:
    - Names, descriptions, effect on the patient, actions taken to prevent recurrence
    - Whether patient was notified
  - Notify referring physician and patient along with the consequences of the event
  - Provide necessary remedial care to patient
  - Retain records of misadministrations for 5 years

KDHE RADIATION CONTROL CONTACT INFO

- 785-296-1560
- FAX 785-296-0984
- Brent Gordy 785-296-6344
- bgordy@kdhe.state.ks.us
- WEB SITE http://www.kdheks.gov/radiation

THE END
QUESTIONS?




The Far Side
Theme-a-Month
1999
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Warheads
MISSILE
Gary Larson